UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BEGLEY, PATRICIA,

Plaintiff,

v.

BRISTOL-MYERS SQUIBB CO., et al.,

Defendants.

Civil Action No. 06-6051 (FLW)

NABER, MICHAEL,

Plaintiff,

v.

BRISTOL-MYERS SQUIBB CO., et al.,

Defendants.

Civil Action No. 06-6269 (FLW)

OPINION

WOLFSON, District Judge:

This matter comes before the Court on two separate motions to dismiss pursuant to Rule 12(b)(6) and Rule 9(b) of the Federal Rules of Civil Procedure brought by defendants Bristol Myers-Squibb Company, Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc., (collectively, "Defendants"). Plaintiffs Patricia Begley and Michael Naber (collectively, "Plaintiffs") bring separate suits against Defendants alleging that they suffered injuries as a result of Defendants' unlawful conduct in connection with the design, development, manufacture, testing,

packaging, promoting, marketing, distributing, labeling and sale of the prescription drug Plavix.[1] In that respect, each of Plaintiffs' First Amended Complaints ("Amended Complaint") asserts various Illinois state and common law claims against Defendants. In the present matter, Defendants move to dismiss Count V, i.e., negligent misrepresentation claim and Count VI, i.e., fraud claim pursuant to the Illinois Consumer Fraud and Deceptive Business Practices Act, Ill. Comp. Stat. Ann. Chapter 815 § 505/1, et seq., asserted by each of the plaintiffs. For the reasons that follow, Defendants' motions to dismiss these counts are granted.

BACKGROUND FACTS

I. Procedural History

Plaintiffs, citizens of Illinois, filed two separate complaints against Defendants asserting claims under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, et seq., the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, et seq., the New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.9, et seq., the New Jersey Uniform Commercial Code, N.J.S.A. 12A:2-313, and the common law of the State of New Jersey, invoking this Court's diversity jurisdiction. See Plaintiffs' Complaints, ¶¶ 6-8. Plaintiffs are among the individual claimants[2] that lodged separate complaints[3] against Defendants in this district between October 2006 and March 2007, invoking this Court's

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[1] Although Plaintiffs bring separate suits against Defendants, this Opinion addresses Defendants' motion as to both Plaintiffs because Plaintiffs assert identical Illinois state law claims.

[2] Initially, claims were filed in twenty-four individual cases, however, a Michigan plaintiff in the matter of Felmlee v. Bristol-Myers Squibb Co., No. 06-6240, voluntarily dismissed her claim in February, 2008.

[3] A number of the twenty-three claimants were joined in their actions by spouses asserting claims for loss of consortium.

diversity jurisdiction and asserting similar claims under New Jersey law based upon injuries allegedly suffered as a result of Defendants' alleged negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and/or the sale of Plavix. Id. A brief recitation of the procedural history in the related matters is necessary to a full understanding of the prolonged procedural history in this matter.

In January 2007, Defendants filed motions to dismiss pursuant to Fed.R.Civ.P. 12(b)(6) in the matters of Hall v. Bristol-Myers Squibb, No. 06-CV-5203 (hereinafter, "Hall"), and Skilstaff v. Bristol-Myers Squibb, No. 06-CV-4965 (hereinafter, "Skilstaff")[4], and indicated their intention to file similar motions in the other Plavix cases pending before this Court. In March 2007, this Court, without objection from the parties, administratively terminated Defendants' motions in Hall and Skilstaff having determined that two cases then pending before the New Jersey Supreme Court addressed the central issues to be decided by this Court on Defendants' motions to dismiss. The parties further agreed that all Plavix cases filed in this district be held in abeyance. Following the issuance of the New Jersey Supreme Court's decisions in Rowe v. Hoffman-LaRoche, 189 N.J. 615 (2007), and International Union of Operating Engineers, Local #68 v. Merck, 192 N.J. 372 (2007), the plaintiff in Skilstaff voluntarily dismissed the action and this Court granted Defendants' request to file a single omnibus motion to dismiss applicable to all personal injury Plavix lawsuits then pending in this district.

One of the main issues to be determined by this Court in the omnibus motion was the federal

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[4] The plaintiff in the matter of Skilstaff v. Bristol-Myers Squibb, is not among the twenty-three individual claimants seeking damages for personal injuries, rather Skilstaff was an Alabama third-party payor seeking certification of a class of third-party payors for violations of the New Jersey Consumer Fraud Act.

preemption of the plaintiffs' individual state law claims. In February 2008, however, in light of the fact that the Third Circuit had pending two separate cases, Colacicco v. Apotex, Inc., and McNellis ex. rel. DeAngelis v. Pfizer, Inc., on its docket regarding substantially similar preemption issues, as did the United States Supreme Court, Levine v. Wyeth, this Court administratively terminated the personal injury Plavix cases pending in this district and permitted plaintiffs to re-file amended complaints in the event there were viable claims after the decisions from the Higher Courts. Following the issuance of the Supreme Court's decision in Levine v. Wyeth, __ U.S. __, 129 S.Ct. 1187, 173 L.Ed. 2d 51 (2009), this Court reinstated the closed cases and, on May 1, 2009, each of the plaintiffs filed an amended complaint. In the amended complaints, each individual plaintiff brought claims under the laws of the states in which they reside, rather than New Jersey, as originally plead. Thereafter, Defendants moved to dismiss certain counts of the amended complaint filed by each individual plaintiff. It is the Defendants' motions to dismiss both Plaintiffs' Counts V and VI that this Court now considers.

II. Factual Background

The following version of events assumes Plaintiffs' allegations in their Amended Complaints to be true because Defendants move pursuant to Fed. Civ. R. P. 12(b)(6). The Court will recount only those facts relevant to the present matter.

Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc. (collectively, the "Sanofi Defendants") partnered with Bristol-Myers Squibb Company ("BMS") to manufacture and market Plavix in the United States. See Amended Complaint ("Am. Compl."), ¶¶

2-5.[5] In April 1997, the Sanofi Defendants and BMS applied for a rare, priority regulatory review by the Food and Drug Administration ("FDA") clearing the way for Defendants to bring Plavix to market in November 1997. Id., ¶ 12. According to Plaintiff, Defendants heavily marketed Plavix directly to consumers through television, magazine, and internet advertising, falsely touting Plavix "as a 'super-aspirin' that would give a person even greater cardiovascular benefits than a much less expensive, daily aspirin, while being safer and easier on a person's stomach than aspirin." Id., ¶ 14. Plaintiffs allege that Defendants either knew or should have known, based upon their own studies, that not only was Plavix not more efficacious than aspirin in terms of preventing heart attacks and strokes, the risk of suffering a heart attack, stroke, internal bleeding, blood disorder or death far outweighed any benefit from the drug. Id., ¶ 15.

As evidence that Defendants were indeed aware of their false and misleading promotion of Plavix, Plaintiffs point to a November 1998 letter from the FDA wherein the FDA instructed Defendants to cease promoting Plavix for off-label use in patients undergoing coronary artery stent placement.[6] Id., ¶ 19. Plaintiffs also point to the same FDA reprimand wherein Defendants were instructed to cease promoting Plavix at an off-label dose, which was nearly four (4) times that of the recommended dosage. Id. In addition to criticizing Defendants for promoting Plavix for unapproved use, the FDA also criticized Defendants for overstating the safety profile of Plavix with respect to its use with other drugs. Id., ¶ 20. In particular, Plaintiffs point to the fact that Defendants touted the safety of Plavix when combined with aspirin (known as "dual therapy") when, in fact, its safety

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[5] Because both Plaintiffs' Amended Complaints are substantially identical, the Court will refer to them collectively, unless otherwise noted.

[6] As discussed more fully infra, the Court will consider the extrinsic documents referenced in the FAC as they were explicitly relied upon by Plaintiff in the FAC.

had not been established. Id. According to Plaintiffs, Defendants' claim regarding the safety of dual therapy has now been proven to be untrue in a recent study published in the New England Journal of Medicine in April 2006 entitled Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance (the "CHARISMA Study"[7]). Id.

As further evidence of Defendants' allegedly false and misleading promotional practices, Plaintiffs point to a December 1998 letter from the FDA, wherein the FDA demanded that Defendants cease the distribution of advertising materials that claimed that Plavix has been proven to be more effective than aspirin. Id., ¶ 21. The FDA criticized Defendants' materials as an overstatement of efficacy, which was unsubstantiated and lacking in fair balance. Id. Again in 2001, the FDA ordered Defendants to immediately cease distribution of promotional material that made false or misleading claims about Plavix. Id., ¶ 22. Specifically, the FDA noted that the clinical evidence of the efficacy of Plavix is derived from Defendants' study entitled Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events Trial (the "CAPRIE Study"). Id. Defendants' promotional material depicted a 19.2% relative risk reduction for Plavix versus aspirin, yet the actual findings of the CAPRIE Study were that Plavix was not proven to be significantly more effective than aspirin. Id. Additionally, the FDA again instructed Defendants to cease claiming that the use of Plavix combined with aspirin was safe and effective. Id.

According to Plaintiffs, in addition to misinforming physicians and consumers through false and misleading promotional materials and advertising, Defendants' drug representatives also misinformed physicians regarding the proper types of patients who should be prescribed Plavix, the

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[7] The CHARISMA Study derives its name from the Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance trial, which was the subject of the article.

duration of its proper usage and the applications for which Plavix is safe and FDA approved. Id., ¶ 23. Specifically, Plaintiffs point to the fact that the drug representatives have encouraged physicians to prescribe Plavix to a broad population who would receive the same therapeutic benefit from aspirin alone, without the purported risk of death, and to use Plavix for unapproved applications. Id., ¶ 24.

Plaintiffs allege that after a nearly eight-year run of misleading physicians and the public regarding the safety and efficacy of Plavix, scientific studies now reveal that Plavix is in fact dangerous. Id., ¶ 26. Citing a study published in The New England Journal of Medicine in January 2005, entitled Clopidogrel versus Aspirin and Esomeprazole to Prevent Recurrent Ulcer Bleeding (the "Chan Study"), Plaintiff notes the dangers of Plavix. Specifically, Plaintiffs contend that the Chan Study demonstrates the fallacy of Defendants' assertions that Plavix is safer and more effective for patients suffering from gastrointestinal intolerance to aspirin. Id., ¶ 27. Plaintiffs point out that the Chan Study recommended that prescribing guidelines for Plavix be changed so that patients would not erroneously believe that Plavix is safer on the stomach than aspirin, in light of the Study's findings that recurring stomach bleeding was 8.6% in the Plavix group versus only .7% in the aspirin group. Id. Plaintiffs additionally cite to the Chan Study's finding that an aspirin a day plus esomeprazole (the generic name for an inexpensive over-the-counter proton pump inhibitor such as Prilosec) is far more cost effective than paying for the four-dollar per day Plavix pill, which greatly increases the risk of stomach bleeding. Id., ¶28. Finally, citing the CHARISMA Study, Plaintiffs contend that Plavix plus aspirin ("dual therapy") is only minimally more effective than aspirin plus placebo at preventing atherothrombotic events, and more significantly, does more harm than good in those patients without peripheral arterial disease or acute coronary syndrome in that it poses a 20%

increased risk to the patient of suffering bleeding injuries, heart attacks, stroke and death. Id., ¶ 29.

Due to these alleged illegal practices, each Plaintiff asserts, inter alia, a fraud claim pursuant to the Illinois Consumer Fraud and Deceptive Business Practices Act, Ill. Comp. Stat. Ann. Chapter 815 § 505/1, et seq. (the "Consumer Fraud Act"), and an Illinois state common law claim of negligent misrepresentation; these claims are the subject of this motion. In connection with these two claims, Plaintiff Begley alleges that she "was prescribed Plavix plus aspirin (dual therapy) on or around January of 2006, Plaintiff felt ill and had to be taken by the paramedics to the hospital because she was bleeding internally." Plaintiff Begley further alleges that "[s]he was transfused blood and had to stay in the hospital for a week, followed by another week in a skilled nursing facility." See Begley Amended Complaint, ¶ 31 (hereinafter referred to as "Begley Compl.").

In a similar fashion, Plaintiff Naber alleges that he "was prescribed Plavix plus aspirin (dual therapy) on or around September, 2005, [in] connection with stent placement for his mild atherosclerotic disease. On or around November of 2005, he went to the hospital complaining of flu-like symptoms." Plaintiff Naber further alleges that "it was determined that he had Thrombotic Thrombocyoptnic Purpura (TTP) blood disorder associated with Plavix." Thereafter, Plaintiff Naber received ten treatments of plasmapheresis. See Naber Amended Complaint, ¶ 31 (hereinafter referred to as "Naber Compl.").

As result of the alleged injuries, Plaintiffs, in Count VI of their respective Amended Complaints, allege that Defendants violated the Consumer Fraud Act by making "deceptive and false representations and misrepresentations of material fact and concealed, suppressed or omitted material facts from the public, including Plaintiff[s], concerning the use and safety of Plavix, with the intent that others rely upon the concealment, suppression or omission of such material facts." Am. Compl.,

¶ 99. In that connection, Plaintiffs allege that "Defendants knew and should have known, that Plavix was unreasonably dangerous and defective, and had a propensity to cause serious and potentially life threatening side effects." Id., ¶ 97. Specifically, Plaintiffs allege that "Defendants' practices relating to their promotion of Plavix were deceptive as they made and/or reinforced a false impression as to its safety." Am. Compl., ¶ 101. Plaintiffs further allege that "Defendants' statements and omissions were made with the intent that the Plaintiff[s], and Plaintiff[s'] prescribing physician[s], would rely on them." Am. Compl., ¶ 102. As a result of the alleged illegal practices, Plaintiffs claim that they have "suffered ascertainable loss-economic loss that includes the purchases of Plavix and additional out-of-pocket healthcare related costs, for which the Defendants are liable to the Plaintiff[s] for treble Plaintiff[s'] actual damages." Am. Compl., ¶ 104.

Similarly, Count V alleges that "Defendants falsely represented to Plaintiff[s] in direct to consumer advertising and indirectly through misrepresentations to the prescribing physician[s], that Plavix was safe and effective. The representations by Defendants were in fact false and Plavix was not safe and was in fact dangerous to Plaintiff[s'] health." Am. Compl., ¶ 77. Each Plaintiff claims that "[a]t the time the representations were made, Defendants concealed from Plaintiff[s] and Plaintiff[s'] prescribing physician[s] information about the propensity of Plavix to cause great harm." Id., ¶ 79. In that regard, Plaintiffs allege that "Defendants' misrepresentations were made by Defendants with the intent to induce Plaintiff[s] to use Plavix, to Plaintiff[s'] detriment." Id., ¶ 81. Plaintiffs further allege that "Defendants' misrepresentations were made to Plaintiff[s], as well as the general public. Plaintiff[s] and Plaintiff[s'] healthcare provider justifiably relied on Defendants' misrepresentations and consequently, Plaintiff[s'] ingestion of Plavix [were] to Plaintiffs' detriment." Id., ¶ 86.

Defendants move to dismiss Count V, the negligent misrepresentation claim, and Count VI, the Consumer Fraud Act claim, of both of Plaintiffs' Amended Complaints. The Court will now address the sufficiency of these claims.

DISCUSSION

I. Standard of Review

When reviewing a motion to dismiss on the pleadings, courts "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008) (citation and quotations omitted). In Bell Atlantic Corporation v. Twombly, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), the Supreme Court clarified the 12(b)(6) standard. Specifically, the Court "retired" the language contained in Conley v. Gibson, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Id. at 561 (quoting Conley, 355 U.S. at 45-46). Instead, the factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." Id. at 555. As the Third Circuit has stated, "[t]he Supreme Court's Twombly formulation of the pleading standard can be summed up thus: 'stating ... a claim requires a complaint with enough factual matter (taken as true) to suggest' the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element." Phillips, 515 F.3d at 234 (quoting Twombly, 127 S.Ct. at 1965).

In affirming that Twombly standards apply to all motions to dismiss, the Supreme Court recently explained the principles. "First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009); Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009).[8] "Second, only a complaint that states a plausible claim for relief survives a motion to dismiss." Id. at 1950. Therefore, "a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." Id. Ultimately, "a complaint must do more than allege the plaintiff's entitlement to relief. A complaint has to 'show' such an entitlement with its facts." Fowler, 578 F.3d at 211.

Before reaching the merits of Plaintiffs' claims, there is a threshold procedural question as to the documents and exhibits this Court may consider on this motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6). As previously referenced in this Court's discussion of the Factual Background, Plaintiffs supply this Court with several exhibits, including: (1) a December 1998 FDA letter addressed to Sanofi Pharmaceuticals, Inc.; (2) a copy of the CHARISMA Study; (3) a November 1998 FDA letter addressed to Sanofi Pharmaceuticals, Inc.; (4) a May 2001 FDA letter addressed to Sanofi-Synthelabo Inc.; (5) the Chan Study; and (6) a Mediation Letter dated March 12, 2009. Additionally, Defendants provide the Court with the November 17, 1997 approval letter for Plavix. While generally a court may not consider matters outside the pleadings when ruling on a motion to dismiss, documents that are "integral to or explicitly relied upon in the complaint" may indeed be

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[8] The Court notes that because the briefing in this matter was filed shortly after the United States Supreme Court's decision in Ashcroft, counsel for Defendants moved for leave to file supplemental briefing addressing the standard of review applicable to the instant motion. This Court found additional briefing unnecessary and, accordingly, denied Defendants' request.

considered without converting a motion to dismiss into a motion for summary judgment. In re Rockefeller Ctr. Props., Inc. Sec. Litig., 184 F.3d 280, 287 (3d Cir.1999) (emphasis and citations omitted). Accordingly, the referenced exhibits are properly before the Court on the instant motion to dismiss.

II. The Consumer Fraud Act Claim

A. Statutory Exemption

At the outset, Defendants submit that Plaintiffs' Consumer Fraud Act claims should be dismissed because Defendants are exempt from liability pursuant to § 10b(1) of the Act. This provision excludes from liability "actions . . . specifically authorized by laws administered by any regulatory body or offices acting under statutory authority of this State or the United States." 815 Ill. Comp. Stat. 505/10b(1). With respect to the application of this particular provision, the Seventh Circuit, in Bober v. Glaxo Wellcome Plc. 246 F.3d 934, 940 (7th Cir. 2001), surveyed numerous Illinois state court decisions in this context and determined that:

> the state [Consumer Fraud Act] will not impose higher disclosure requirements on parties than those that are sufficient to satisfy federal regulations. If the parties are doing something specifically authorized by federal law, section 10b(1) will protect them from liability under the CFA. On the other hand, the CFA exemption is not available for statements that manage to be in technical compliance with federal regulations, but which are so misleading or deceptive in context that federal law itself might not regard them as adequate.

Id. As the Illinois Supreme Court has noted. "mere compliance with applicable law does not necessarily bar Consumer Fraud Act liability. Instead, the conduct at issue must be specifically authorized." Price v. Philip Morris, Inc., 219 Ill. 2d 182, 249 (2006).

This Court is not prepared at this stage in the litigation to engage in the legal analysis necessary to determine the applicability of § 10b(1). While this Court's interpretation of the

meaning of § 10b(1) is a question of law, Defendants' assertions that its conduct was authorized by the FDA necessarily interjects an analysis of the regulatory scheme applicable to the alleged deceptive promotional materials that has not been adequately briefed by the parties on these motions. Defendants have provided the Court with no support or authority for its bald assertion that "any action involving Plavix would be authorized or administered by FDA." The fact that the FDA regulates the labeling and marketing of pharmaceuticals is not a fait accompli to the application of the exemption. While the FDA may indeed regulate the promotion and marketing of Plavix, the parties have failed to provide the Court with any factual information or legal analysis involving the regulatory scheme at issue. The issue for this Court's determination is whether the promotional materials that Plaintiffs identify as deceptive were nevertheless in compliance with FDA regulations governing those materials. If indeed Defendants were compliant, then the Court could find the statutory exemption applicable. If, however, Defendants' promotional materials were not authorized by the FDA's regulatory scheme in that they were either not truly compliant or are not among the type of materials that the FDA monitors then the statutory exemption would be inapplicable. The Court rejects Defendants' assertion that the exemption is applicable merely because the promotion and marketing of prescription drugs are generally regulated by the FDA. In the absence of adequate briefing from the parties as to these issues the Court is not in a position at this juncture to make a ruling on the issue. Accordingly, this Court finds that Plaintiffs' claims under the Consumer Fraud Act should not be dismissed on this basis.

B. Sufficiency of the Pleadings

To state a claim under the Consumer Fraud Act, neither party disputes that Plaintiffs must plead with particularity pursuant to Rule 9(b). Indeed, to assert a violation of the Consumer Fraud

Act, the allegations must be pled with the heightened specificity of Rule 9(b). See Murry v. America's Mortgage Banc, Inc., No. 03-5811, 2004 U.S. Dist. LEXIS 12045, at *17 (N.D. Ill. Jun. 29, 2004); Frye v. L'Oreal USA, Inc., 583 F.Supp. 2d 954, 957 (N.D. Ill. 2008)(citations omitted).

In Frederico v. Home Depot, 507 F.3d 188 (3d Cir. 2007), the Third Circuit elucidated the heightened pleading standard under Rule 9(b):

> Pursuant to Rule 9(b), a plaintiff alleging fraud must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the "precise misconduct with which [it is] charged." To satisfy this standard, the plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation.

Id. at 200 (internal citations omitted); In re Supreme Specialties, Inc. Sec. Litig., 438 F.3d 256, 276-77 (3d Cir. 2006)(the Third Circuit advised that pursuant to Rule 9(b), at a minimum, a plaintiff must support his/her allegations of fraud with all the essential factual background that would accompany "'the first paragraph of any newspaper story' – that is, the 'who what, when, where and how' of the events at issue"(citations omitted)). Moreover, a complaint must do more than assert generalized facts, it must allege facts specific to the plaintiff. Rolo v. City Investing Co. Liquidating Trust, 155 F.3d 644, 658-59 (3d Cir. 1998)(where the complaint failed to allege "what actually happened to either" of the plaintiffs, the complaint did not plead "fraud with the specificity required by Rule 9(b)"). This type of heightened pleading requirement is in accord with the Seventh Circuit precedent. DiLeo v. Ernst & Young, 901 F.2d 624, 627 (7th Cir. 1990).

In order to state a claim for a violation of the Illinois Consumer Fraud Act, Plaintiffs must allege that: (1) the defendant engaged in a deceptive act or practice, (2) the defendant intended that the plaintiff rely on that deception, (3) the deception occurred in the course of conduct involving

trade or commerce, and (4) the act proximately caused damage to the plaintiff. Jenkins v. Mercantile Mortgage Co., 231 F. Supp. 2d 737, 747 (N.D. Ill. 2002). "Showing a plaintiff's actual reliance is not an element of statutory consumer fraud under the Act, but a valid claim must still show that the consumer fraud proximately caused her injury." Celex Group, Inc. v. Executive Gallery, Inc., 877 F. Supp. 1114, 1128 (N.D. Ill. 1995). Omissions or concealment of material facts in the conduct of trade or commerce constitutes consumer fraud. See 815 Ill. Com. Stat. 505/2. "A material fact exists where a buyer would have acted differently knowing the information, or if it concerned the type of information upon which a buyer would be expected to rely in making a decision whether to purchase." Murry, 2004 U.S. Dist. LEXIS 12045 at *19 (citing Mackinac v. Arcadia Nat'l Life Ins. Co., 271 Ill. App. 3d 138 (Ill. App. Ct. 1995)).

In their Amended Complaints, Plaintiffs allege a unified course of fraudulent conduct and they rely entirely on that as the basis of their Consumer Fraud Act claims. More specifically, as noted above, Plaintiffs allege that Defendants "knew or should have known, that Plavix was unreasonably dangerous or defective, and had a propensity to cause serious potentially life threatening side effects."[9] Plaintiffs further allege that "[d]espite their knowledge, the Defendants omitted material facts in the disclosures they made to the public, the medical community and consumers, including the Plaintiff[s], concerning the use and safety of Plavix." As a result, Plaintiffs allege that Defendants violated the Consumer Fraud Act "in that they made deceptive and false representations and misrepresentation of material fact and concealed, suppressed or omitted material facts from the public, including the Plaintiff[s], concerning the use and safety of Plavix." Plaintiffs'

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[9] Since the Court is restating these allegations that were previously set forth in this Opinion, the Court will not repeat the citations to the record here.

allegations fall short of complying with Rule 9(b).

Arguing the contrary, Plaintiffs maintain that their Amended Complaints assert sufficient facts to satisfy Rule 9(b). In particular, Plaintiffs point to ¶¶ 19-22, 23-27, 29-31 and 93-105 of their Amended Complaints to support their assertion that they have pled the so-called "newspaper requirements" of Rule 9(b). Summarizing their points, Plaintiffs state (1) that they have alleged who made the misleading statements - Defendants; (2) that they have alleged what was misleading about Defendants' statements - Defendants advertised Plavix as safe and effective in "dual therapy" treatments, off-label use, and more effective than aspirin; (3) that they have alleged that Defendants' statements were known to be misleading or should have been known when made - multiple FDA warnings against deceptive advertising of Plavix's safety and use in certain treatments, as well as scientific studies, both internal and external, refuting Defendants' wrongful advertising of Plavix; (4) that they have alleged what Defendants' misrepresentations were - the safety and effectiveness of Plavix as advertised in the face of both FDA warnings to the contrary and numerous scientific studies; and (5) that they have alleged why Defendants' misrepresentations were misleading - concealment of the risks associated with the use of Plavix, promotion of the safe and beneficial use of Plavix for off-label use in patients receiving arterial stents, even though the FDA and scientific studies warned against such use. Nevertheless, Plaintiffs also suggest that under the circumstances of this case, because information regarding their allegations of fraud are within Defendants' control, less specificity of pleading is required pending discovery.

Although Plaintiffs have arguably pled with particularity with respect to the first, second and third elements of a Consumer Fraud Act claim, they have failed to sufficiently plead the fourth element - that the alleged illegal act proximately caused damage to Plaintiffs. Indeed, Plaintiffs

made exhaustive allegations regarding Defendants' alleged illegal practices by relying on FDA correspondence and scientific studies; however, the Amended Complaints fail to allege with specificity the connection between Defendants' conduct and Plaintiffs' resultant injury. Plaintiffs' only allegations particular to their circumstances that support their statutory fraud claims can be found in ¶ 31 of the Amended Complaints, wherein Plaintiffs set forth when they were prescribed Plavix and the health issues as a result of taking Plavix. These allegations are insufficient to meet the rigors of Rule 9(b).

Plaintiffs fail to identify any specific advertisements they viewed, how they were misled by these advertisements, how these advertisements affected their prescriptions for Plavix and how these advertisements caused any of their injuries. In other words, both of the Amended Complaints fail to identify which, if any, of the promotional or marketing materials were received, viewed or relied upon by Plaintiffs, and if they were, when these materials were viewed and how they were relied upon. More simply stated, Plaintiffs have failed to allege any specific facts establishing a connection between the alleged conduct of Defendants and the alleged injury claimed. See Kritley v. Wadekar, No. 05-5383, 2006 U.S. Dist. LEXIS 60309, at *9-10 (D.N.J. Aug. 25, 2006)("Plaintiffs offer only general, conclusory statements that Plaintiffs purchased pharmaceutical products manufactured by the company that Defendants were officers and directors of, and that Defendants marketed the products using false representations, with fraudulent scienter." Plaintiffs do not allege with particularity any of the facts that would be expected to be within their knowledge: exactly who bought exactly what product when, relying on what false representations made when by whom"); Guilbealt v. R.J. Reynolds Tobacco Co., 84 F.Supp. 2d 263, 269 (D.R.I. 2000)(when a plaintiff claims that a product advertisement or promotion led to injuries, he or she must "identify specific

advertising he [or she has] seen and how it ha[s] affected" him or her to comply with Rule 9(b)'s requirements).

Likewise, Plaintiffs fail to allege that their physicians personally received a misrepresentation of fact from Defendants and relied upon that misrepresentation in deciding to prescribe Plavix to their respective plaintiff patients.[10] Rather, Plaintiffs allege only generally that Defendants "omitted material facts in the disclosures they made to the public, the medical community and to consumers, including the Plaintiff[s], concerning the use and safety of Plavix," and these "statements and omissions were made with the intent that the Plaintiff[s], and Plaintiff[s'] prescribing physician[s], would rely on them." Although the Amended Complaints also allege that Defendants' drug representatives have misinformed physicians about the proper types of patients who should be given Plavix, the duration of its proper usage, and the applications for which it is safe and FDA approved, Plaintiffs have not identified the representatives, what was said, when it was said, to whom it was said and how these statements relate to Plaintiffs' prescriptions of Plavix.

Moreover, these factual allegations are not the type of facts that are within the control of, and therefore subject to concealment by Defendants. Instead, these important details regarding misrepresentations made to, and relied upon by, Plaintiffs and their physicians are within Plaintiffs' ken, but are nowhere to be found within their respective Amended Complaint.[11]

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[10] Plaintiffs' Amended Complaints do not provide the names of their prescribing physicians.

[11] Indeed, in that connection, each Plaintiff is uniquely equipped to determine from their physician whether the physician received such promotional literature. Even where factual information may be within the domain or control of Defendants, such as the identities of the doctors who received promotional information, Plaintiffs must still "accompany their legal theory with factual allegations that make their theoretically viable claim plausible." In re Burlington Coat Factory, 114 F.3d 1410, 1418 (3d Cir. 1997). Moreover, to "avoid dismissal," a complaint

The deficiencies of Plaintiffs' Amended Complaints in this context were recently discussed by the court in In re Schering-Plough Corp. Intron/Temodar Consumer Class Action, No. 06-5774, 2009 U.S. Dist. LEXIS 58900 (D.N.J. Jul. 10, 2009) (Chesler, J.) In that case, plaintiffs filed a class action complaint alleging, inter alia, that defendants "engaged in improper and illegal off-label promotion of Intron-A, PEG-Intron, Rebetol and Temodar." Id. at *6. Plaintiffs further alleged that defendants "orchestrated a campaign to illegally market and promote the Subject Drugs for off label uses . . . and, as a result, Plaintiffs paid for drugs at an inflated price or for drugs that they would not have purchased but for the illicit marketing scheme." Id. at *7. Similar to Defendants' response here, the defendants there filed a motion to dismiss, among other claims, plaintiffs' fraud and negligent misrepresentation claims.

In dismissing these two specific claims, the court, in a well-reasoned opinion, found that plaintiffs made "sweeping allegations" regarding defendants' alleged promotion, yet they did not plead a single instance in which they, themselves, or any of their prescribing doctors received a misrepresentation of fact on which they relied upon in either taking or prescribing any of the subject drugs. Id. at *117. In addition, the court explained that plaintiffs' common law fraud and negligent misrepresentation claims also failed to state a claim because plaintiffs did not allege a causal connection between their injury and defendants' conduct. Id. at *119. While In re Schering-Plough dealt with New Jersey's common law claims, the same reasoning applies here since the fraud theory

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must also delineate at least the nature and the scope of a plaintiff's efforts to obtain, before filing the complaint, the information needed to plead with particularity. Shapiro v. UJB Financial Corp., 964 F.2d 272, 285 (3d Cir. 1992). Plaintiffs have failed to comply with these requirements. Indeed, Plaintiffs' Amended Complaints contain no allegations that the information required for Plaintiffs to meet Rule 9(b) obligation is solely within Defendants' control.

of that case parallels the instant actions. See Suarez v. Playtex Products, Inc., No. 08-2703, 2009 U.S. Dist. LEXIS 63774, at *8-10 (N.D. Ill. Jul. 24, 2009)(plaintiffs failed to allege with specificity "whether or when they relied on, or even saw, these [misrepresentations] prior to purchasing the coolers"). Accordingly, Plaintiffs fail to inject precision and some measure of substantiation to support their Consumer Fraud Act claim, and therefore, they are dismissed without prejudice.

III. Negligent Misrepresentation

Defendants submit that Plaintiffs' claims of negligent misrepresentation fail because Defendants do not owe a duty to Plaintiffs to communicate accurate information. Indeed, under Illinois law a defendant may be liable for negligent misrepresentation only if it "is in the business of supplying information for the guidance of others in their business transactions." Moorman Mfg. Co. v. National Tank Co., 91 Ill. 2d 69, 89 (1982); see Orix Credit Alliance, Inc. v. Taylor Machine Works, Inc., 125 F.3d 468, 475 (7th Cir. 1997). Defendants argue that they are in the business of manufacturing pharmaceutical drugs, not informational services, and therefore, their actions fall outside the scope of a negligent misrepresentation claim. The case law supports this argument.

Courts applying Illinois law consistently have rejected negligent misrepresentation claims brought against manufacturers of tangible, noninformational goods, on the grounds that they are not in the business of supplying information. See, e.g., Orix, 125 F.3d at 475-77; Coleman Cable Systems, Inc. v. Shell Oil Co., 847 F. Supp. 93, 95-96 (N.D. Ill. 1994) (collecting cases); Knox College v. Celotex Corp., 117 Ill. App. 3d 304 (Ill. App. Ct. 1983). In other words, "when the information offered by the defendant relates to the defendant's tangible goods and/or noninformational goods or services, the information is considered merely ancillary or incidental, and the defendant is not deemed to be in the business of providing information and is not liable for

negligent misrepresentation." ABN AMRO, Inc. v. Capital Int'l, Ltd., 595 F. Supp. 2d 805, 853 (N.D. Ill. 2008).

However, this rule is not without exceptions. Most producers of tangible goods also provide information to their customers. In such circumstances, Illinois courts make a case-by-case determination of whether a party is in the business of selling goods or of supplying information, with focus on "whether the information furnished with the noninformational goods was central to the business transaction" or "merely incidental to the sale of goods." Coleman, 847 F. Supp. at 95-96; see Orix, 125 F.3d at 475-76; Village of Lake Barrington v. Koch Materials Co., No. 00-736, 2000 U.S. Dist. LEXIS 10438, at * 4-5 (N.D. Ill. Jul. 13, 2000).

The Illinois Supreme Court's test for determining whether a defendant "is in the business of supplying information for the guidance of others in their business transactions is whether the end product of the relationship between plaintiff [and defendant] is a tangible object (i.e., a product) which could be readily described in a contract or whether it is intangible." Castrol Indus. N. Am., Inc. v. Airosol Co., No. 01-1077, 2002 U.S. Dist. LEXIS 17192, at *9 (N.D. Ill. Sep. 11, 2002)(citations and quotations omitted). "[I]f the intended end result of the plaintiff-defendant relationship is for the defendant to create a product, a tangible thing, then the defendant will not fit into the business of supplying information negligent misrepresentation exception . . . ." Id. (citations and quotations omitted).

Here, Defendants' pharmaceutical products, including Plavix, are tangible goods. Insofar as Defendants provide information in connection with the marketing and sale of Plavix, that information is only incidental to Defendants' primary objective of selling Plavix. Illinois precedent instructs that this type of common business practice does not transform Defendants into suppliers

of business information such that negligent misrepresentation liability is triggered. See Orix, 125 F.3d at 475-76 (supplier of machine not liable for alleged misrepresentations regarding appraisal of machine); Coleman, 847 F. Supp. at 95-96 (supplier of plastic insulation not liable for alleged misrepresentations regarding compatibility of insulation with other compounds); Knox, 117 Ill. App. 3d at 308 (supplier of roofing materials not liable for alleged misrepresentations regarding quality of product). Accordingly, as suppliers of noninformational goods, Defendants cannot be subject to a negligent misrepresentation cause of action. Accordingly, Plaintiffs' negligent misrepresentation claims are dismissed.

CONCLUSION

Based upon the foregoing reasons, Defendants' motions to dismiss Count V and Count VI of both Plaintiffs' Amended Complaints are granted. However, with respect to only Count VI – the Consumer Fraud Act claim – Plaintiffs shall have leave to file separate motions to amend the Amended Complaint if they seek to assert such a claim, but they must cure the deficiencies as outlined by the Court.

DATE: December 30, 2009

/s/ Freda L. Wolfson
The Honorable Freda L. Wolfson
United States District Judge